

EXHIBIT 14

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
NORTHERN DIVISION

NOVARTIS PHARMACEUTICALS)
CORPORATION,)
Plaintiff,)

vs.)

CIVIL CASE NO.
1:24-cv-01557-MJM

ANTHONY G. BROWN, in his)
official capacity as)
ATTORNEY GENERAL OF THE)
STATE OF MARYLAND,)

and)

KRISTOPHER RUSINKO, in his)
official capacity as)
BOARD PRESIDENT OF THE)
MARYLAND BOARD OF PHARMACY,)
Defendants.)

MONDAY, JULY 1, 2024
Courtroom 5C
Baltimore, Maryland

TRANSCRIPT OF PROCEEDINGS
PRELIMINARY INJUNCTION HEARING
BEFORE THE HONORABLE MATTHEW J. MADDOX

For the Plaintiff (via Zoom):

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(Computer-aided Transcription of Stenotype Notes)

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1 drugs to the contract pharmacy as it appears that Subsection, I
2 guess, (c) of the statute would require them to?

3 MR. DIETRICH: As I understand it, it would mean that
4 they are not honoring the price --

5 THE COURT: Right.

6 MR. DIETRICH: -- that's set forth in the 340B
7 program.

8 THE COURT: Okay.

9 MR. DIETRICH: And so we're hearing the word "price"
10 but it's not -- H.B. 1056 is not a price-setting statute.

11 THE COURT: That's my point. So how would it be a
12 violation for them to charge regular price for a 340B drug?
13 How would that be a violation of the Maryland statute?

14 MR. DIETRICH: Because the 340 drug is a drug that's
15 purchased by the covered entity, the provider, online provider,
16 and that they are refusing to honor the price at their contract
17 pharmacy. The covered entity is contracted with CVS or
18 Walgreens or whoever, and the patient of a covered entity is
19 going there and they're not getting the -- their prescription
20 is being filled but it's not getting the price set forth in
21 340B and therefore that benefit that we've talked about does
22 not then go back to the covered entity.

23 THE COURT: But everything that you've just
24 described, the statute doesn't seem to speak to any of that. I
25 concede that 340B itself speaks to it and it sounds like this

1 asked earlier, which is that if they don't honor the discounted
2 price under 340B, that would violate the statute. So their
3 pricing decision, then, is essentially regulated by H.B. 1056.
4 Am I wrong?

5 MR. DIETRICH: But the regulation happened, the price
6 regulation happens out of 340B. So you have this program, this
7 federal program that sets the prices and then you have state
8 law that expands the access.

9 THE COURT: Right. So it sounds like, like I was
10 saying earlier, that their pricing decision could violate 340B,
11 but it's not clear to me how it would violate the new Maryland
12 law because the Maryland law, like you said, doesn't speak to
13 pricing.

14 MR. DIETRICH: I mean, it could violate 340B, but I
15 think that's where the Novartis and the Sanofi cases could come
16 into play in terms of their claim that we don't need to under
17 the statute, the statute's silent as to restrictions that we,
18 drug companies, can place on the relationship between a covered
19 entity and a contract pharmacy, and we as drug companies can
20 put those restrictions there.

21 And so if they can put those restrictions there, then
22 they -- under 340B alone, there would be situations where a
23 covered entity's patient would go to a pharmacy, a contract
24 pharmacy that they think is a contract pharmacy but is outside
25 of what the drug companies will honor. They don't honor the

1 price there, and under Sanofi and Novartis in the DC Circuit it
2 would not be a violation of 340B per se, because, again, the
3 premise of those cases was that they are allowed under the
4 plain language of 340B to place restrictions.

5 And I'll note that those cases were a little bit more
6 nuanced in terms of no restrictions or they have to abide by
7 any restrictions. It was more -- a lot of them get into the
8 nuance of what an offer for sale is and whether they could
9 completely extinguish any contract pharmacy option for a
10 covered entity. But that's certainly not what this case is
11 about.

12 But as I said, the difference between this case and
13 Association for Accessible Medicines is that there is a
14 Maryland nexus with the Maryland covered entity. The drug is
15 coming here, they own it, they are involved, the covered entity
16 is involved with the transaction between the manufacturer. And
17 simply because you have two players in that transaction that
18 are out of state doesn't override the fact that the end result,
19 the end consumer of those drugs or the person -- the entity
20 that is purchasing those drugs is a Maryland entity that is
21 then serving patients who came to their facilities in Maryland.
22 So the Maryland nexus is what takes us out of the universe of
23 the Accessible Medicines case.

24 THE COURT: So the AAM case identified I guess
25 particular issues that the Court considered Commerce Clause

1 for the Homeless does not have a relationship with respect to
2 that non-Novartis drug.

3 THE COURT: I wanted to use in the hypothetical that
4 they did have the relationship. So say Health Care for the
5 Homeless has a relationship with the pharmacy on the other side
6 of town closer to where their patient lives and therefore, I
7 guess under your law, they have to be able to get that drug at
8 that other pharmacy. Correct?

9 MR. FELDMAN: Exactly.

10 THE COURT: So they get that drug because Novartis is
11 supplying the drug, and where's the violation? Even if
12 Novartis doesn't allow the covered -- even if Novartis charges
13 the covered entity for the regular price, the delivery has been
14 made, so where is the violation?

15 MR. FELDMAN: The violation is they have to deliver
16 at the 340B price, which is what's required by on -- the sale
17 is to the covered entity. I don't want to conflate sale and
18 delivery. They are two separate things.

19 Federal law dictates that 340B drugs be sold to covered
20 entities at the discounted price. In your example, they're
21 delivering to a pharmacy in West Baltimore for a sale to a
22 covered entity at a non-340B price.

23 THE COURT: If it's a non-340B price, then it's not a
24 340B drug, is it?

25 MR. FELDMAN: If it's -- if it's a 340B drug, it has

1 to be sold under federal law at the 340B price.

2 THE COURT: Okay. We are kind of talking about a
3 couple different things. I'm focused on whether this violates
4 the Maryland statute, right? I'm not talking about whether it
5 violates the federal statute.

6 So if the covered entity makes this order based upon your
7 sort of simplified rendering of what happens here, if the
8 covered entity makes the order for the drug to be delivered to
9 the pharmacy on the other side of town and not necessarily
10 Novartis but one of their competitors who may also be bringing
11 suit here says I'm not recognizing the relationship with that
12 pharmacy so I'm not going to charge you the discounted price,
13 I'm charging you regular place, but the drug has already been
14 delivered, the patient picks it up. They haven't impeded any
15 delivery, first of all, and I guess arguably it's not a 340B
16 drug at all because it hasn't been offered at the 340B price.
17 So how could that be a violation of this statute, the Maryland
18 statute?

19 MR. FELDMAN: The violation would be the refusal to
20 deliver at the 340B price if it's a 340B drug.

21 THE COURT: But where does it say that it has to
22 deliver at the 340B price?

23 MR. FELDMAN: Subsection (c) uses the term "shall not
24 limit the acquisition of a 340B drug or delivery of a 340B drug
25 to a pharmacy that is under contract," et cetera, "with a

1 covered entity."

2 THE COURT: But then the 340B drug is defined to
3 include, "has been subject to an offer for reduced prices."
4 And if the manufacturer is charging the regular price, doesn't
5 that take it outside the definition of a 340B drug?

6 MR. FELDMAN: If it hasn't been --

7 THE COURT: Maybe I'm -- I mean, I'm not -- I don't
8 work in this industry. You know, I'm sort of a generalist on
9 this.

10 MR. FELDMAN: Nor do I, Your Honor.

11 THE COURT: You know, I'm just trying to figure out
12 where the violation is because based upon the replenishment
13 model and other models that have been described in the briefs,
14 it sounds like there is no impediment to the delivery and the
15 only thing that the statute regulates, and you keep saying
16 this, the only thing the statute regulates is the delivery.

17 MR. FELDMAN: The delivery of sales of 340B drugs to
18 covered entities.

19 THE COURT: Right.

20 MR. FELDMAN: And so if a covered entity is buying a
21 drug in my simplified transaction, if a covered entity -- but
22 the covered entity says we want it delivered over here, the
23 Maryland law says you have to honor that request.

24 THE COURT: And they deliver it so there's no
25 violation, even if they charge full price.

1 MR. FELDMAN: That is a violation, because they're
2 not delivering the drug at the 340B price.

3 THE COURT: But it doesn't say in the -- this is what
4 I keep coming back to. It doesn't say in the statute that they
5 have to charge the 340B price. If they don't charge the 340B
6 price, then that means it's not by definition a 340B drug, in
7 which case they don't have any obligations to deliver even --
8 any obligations to deliver at all because the delivery
9 obligation only applies to 340B drugs.

10 MR. FELDMAN: I'm not sure I agree with you, Your
11 Honor, respectfully.

12 THE COURT: Okay. But just show me where -- I mean,
13 what letter of the statute is being violated in this scenario.
14 And I'm going to give Ms. Stetson a chance to answer, too,
15 because I posed basically the same question to her and I'm not
16 sure that I understood it. That's why I keep asking it over
17 and over again.

18 MR. FELDMAN: The drug -- federal law requires that
19 certain listed drugs be sold to covered entities at a
20 particular price.

21 THE COURT: Right.

22 MR. FELDMAN: Federal law specifies that price. The
23 state law is saying you can't restrict a covered entity in its
24 request to deliver a drug offered at that price and it has to
25 be offered at that price. There's no choice. It can't be

1 But I take your point. Let me give the State a chance to
2 respond. I know that, you know, you don't -- not necessarily
3 entitled to a reply but there was a lot that was said there
4 that was not brought out in the original argument. I wanted to
5 give the State a chance to offer any rebuttal that you had.
6 But if there's nothing you have, that's fine, too. I just
7 wanted to give you a chance to speak.

8 MR. FELDMAN: No, thank you, Your Honor. I do have a
9 few points.

10 So simply because price might be referred to in the House
11 Bill 1056 does not mean it regulates price. I don't think --
12 it is the federal law that regulates price and simply because
13 the law prohibits discrimination of covered entities' choice of
14 where the 340B price drugs are delivered doesn't mean that the
15 Maryland law regulates price.

16 THE COURT: How can you say it doesn't regulate price
17 if a pricing decision made by the manufacturer could violate
18 the statute? That's the exact meaning of "regulation" that it
19 prescribes certain conduct, and if the conduct is the price
20 that the manufacturer ultimately charges and that runs afoul of
21 the statute, doesn't the statute regulate price?

22 MR. FELDMAN: The conduct is delivery at the
23 federally mandated price.

24 THE COURT: But price is part of it. If they
25 delivered at a different price, you would say that's a

1 violation of the statute. I'm not sure that I read it that
2 way, but that's what you seem to be saying.

3 MR. FELDMAN: That is how we read it.

4 THE COURT: So I'm trying to figure out how you can
5 say, then, it doesn't regulate price if a -- so say you have
6 the exact same conduct, the delivery. The delivery occurs and
7 the only thing that distinguishes a violation -- a violative
8 delivery versus a nonviolative delivery is the price associated
9 with the good, isn't that exactly what you're regulating?
10 Price?

11 MR. FELDMAN: Manufacturers must offer, have no
12 choice, there's a price that's dictated by federal law. They
13 must offer those drugs to the purchaser covered entity.
14 Covered entity says, I want to buy a hundred of Lipitor at this
15 price but I want it delivered over here. If they refuse to
16 deliver it over here, if they say we're not going to sell it to
17 you at that price, we're not going to deliver it here at that
18 price, the violation is the discrimination in the choice of
19 where to deliver the drug at the price that's mandated by
20 federal law.

21 THE COURT: All right. Was there anything else? Any
22 other points you wanted to make?

23 MR. FELDMAN: Yes, a couple points, Your Honor.

24 With respect to the DC -- the decisions by the DC Circuit
25 and the Third Circuit, what was at issue in those cases was,